DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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STATEMENT OF

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"INTERNATIONAL PRESCRIPTION DRUG PARITY; ARE AMERICANS BEING PROTECTED OR GOUGED?"

BEFORE THE

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON HUMAN RIGHTS AND WELLNESS

U.S. HOUSE OF REPRESENTATIVES

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INTRODUCTION

Mr. Chairman and Members of the Committee, I am William K. Hubbard, Associate Commissioner for Policy and Planning at the Food and Drug Administration (FDA or the Agency). Today I am accompanied by John M. Taylor III, FDA's Associate Commissioner for Regulatory Affairs. We are pleased to come before the Subcommittee to discuss the benefits and risks of pharmaceutical sales over the Internet and what the Agency has been doing to address issues related to the sale of drugs from foreign sources.

With greater and greater frequency, consumers are using the Internet to access health related information and products. Sales of consumer products over the Internet have grown rapidly, including the sale of drugs. The growth in online drug sales by reputable pharmacies has provided significant benefits to consumers. Many managed health care organizations are searching for ways to achieve cost savings and are turning to online prescription plans as a means of providing quality service at a lower cost.

Online drug websites, however, also present risks to purchasers and unique challenges to regulators, law enforcement officials and policy makers. FDA is concerned about the public health implications of Internet drug sales, and we are responding to these concerns as we develop and implement risk-based strategies to protect the public health. FDA monitors the Internet to evaluate the quality of information being provided, and we encourage consumers to remain vigilant about their purchases and to rely on reputable Internet sites.

Although other products regulated by the Agency, such as medical devices, medical diagnostics, foods, dietary supplements and animal drugs also are sold online, this testimony will focus on the purchase of prescription drugs from foreign sources, whether this occurs through online sales or other forms of personal importation. We will discuss the advantages and risks, outline FDA's authority and enforcement activities in this area, and describe initiatives we are taking to better respond to the regulatory challenges we face.

In the context of prescription drug sales over the Internet, the private sector also has an important role in promoting consumer education and in providing assurances to consumers about the quality of products and services they offer. Our challenge is to make sure that protection for consumers who purchase prescription drugs in cyberspace with the click of a mouse is just as strong as the protection consumers enjoy when they purchase drugs at their corner pharmacy. Rapid technological developments have magnified the challenges we face. We constantly struggle to design appropriate solutions to meet these challenges. As electronic commerce embraces global markets, we should strive for consistent policies that promote safety regardless of the jurisdiction in which a U.S. consumer resides or the location of the pharmacy.

Let me begin by providing an overview of FDA activities and concerns relating to drugs purchased on the Internet including drugs purchased from foreign sources:

- **OUTREACH AND EDUCATION**: FDA is continuing its campaign to better educate U.S. consumers about the potential risks associated with the purchase of prescription drugs from foreign sources. Consumers take genuine risks when they purchase drugs from Internet sites that dispense foreign drugs or are not licensed and operated under state pharmacy law. These outlets may dispense expired, subpotent, contaminated or counterfeit product, the wrong or a contraindicated product, an incorrect dose, or

medication without adequate directions for use. Unsafe or inappropriate drugs put consumers at risk for dangerous drug interactions and serious health consequences. FDA continues to meet with organizations representing consumer health practitioners and industry. The Agency's website and brochures contain information for consumers on safely purchasing drugs online.

- **WORKING WITH STATES:** State pharmacy boards primarily regulate licensing and the dispensing of drugs at the state level. FDA has been working with the states to address concerns regarding importation of foreign prescription drugs. In February 2003, FDA hosted a nationwide call with 38 state boards of pharmacy, other state regulatory agencies and consumer groups to discuss current Internet drug sale practices. While some state laws are stronger than others, FDA has actively engaged with a number of states in jointly pursuing illegal Internet sites. FDA will continue to expand its cooperative activities with states in order to effectively address the many challenges in this area of electronic commerce.

- **CANADIAN COOPERATION**: FDA is actively working with the Health Canada regarding the increasing number of U.S. pharmacies that are advertising and promoting sales of prescription drugs from Canada. We have asked the Minister of Health to investigate a list of 45 Canadian websites that are selling drugs to U.S. citizens for investigation. We agreed to designate respective agency contacts on this issue and continue our discussions about Internet sales.

- **ENFORCEMENT**: Recent criminal and civil cases are evidence of the seriousness of the risks to public health that regulators uncover when responding to Internet drug sales. To date, FDA has initiated the following actions:

    - 372 Internet drug criminal investigations, 90 involve domestic Internet pharmacies.
    - 150 Internet-related drug arrests, 60 involve Internet pharmacies, and 92 convictions, 26 convictions involve Internet pharmacy cases;
    - 100 open Internet drug criminal investigations; 90 sites are under active review for possible regulatory or civil action;
    - Nearly 200 cyber warning letters have been sent to domestic and foreign online sellers;
    - 5 preliminary injunctions;
    - 15 product seizures;
    - 11 product recalls and the voluntary destruction of 18 illegal products.

BENEFITS OF ONLINE DRUG SALES

The Internet is rapidly transforming the way we live, work, and shop in all sectors of the economy.

In the health sector, tele-medicine allows people in remote areas to access the expertise of doctors

in the nation's finest health centers. The Internet permits individuals to obtain extensive medical information to help them understand health issues and treatment options. Millions of Americans used the Internet last year to find medical information, either in documentary resources or through online discussions with health professionals. Conducting research regarding health concerns is the sixth most common reason that people use the Internet, according to the market research firm, Cyber Dialogue Inc.

The sale of most consumer products over the Internet has grown rapidly in recent years, including the sale of prescription medications. FDA is aware that many reputable Internet pharmacies provide consumers seeking prescription drugs with a measure of safety, privacy and convenience. They provide information on drug interaction, and may e-mail customers if the drug they ordered has been recalled, a cheaper generic version of the drug becomes available or to remind them of prescription renewals. Some sell drugs for less than traditional "brick-and mortar" pharmacies, which is particularly important for people with limited income or without insurance coverage.

Prescription drug sales over the Internet can provide tremendous benefits to consumers. These benefits are many and include:

- Access to drugs for the disabled or otherwise homebound, for whom a trip to the pharmacy can be difficult.
- The convenience of shopping 24 hours a day; and a complete selection of pharmaceutical products.
- Privacy for those who don't want to discuss their medical needs in a public place.

Hyperlinks and search programs provide online customers with written product information and references to other sources of health information more easily than in the traditional storefront.

Finally, as the use of computer technology to transmit prescriptions from doctors to pharmacies expands, a reduction in prescription errors may be possible.

While online pharmaceutical sales are important for some customers, brick and mortar pharmacies can offer benefits and services that are often not available through the Internet, such as immediate access to prescription drugs needed for immediate treatment.

In matters relating to pharmaceutical sales over the Internet, the challenge for government at both the state and Federal level is to develop and implement policies that will allow legitimate electronic commerce to flourish while continuing to assure safety. Consumers must have confidence that protections for online consumers are equivalent to safeguards at brick and mortar pharmacies.

CONCERNS ABOUT ONLINE SALES

As beneficial as this computer technology can be, the Internet also has created a marketplace for the sale of unapproved new drugs, prescription drugs dispensed without a valid prescription, or products marketed with fraudulent health claims. Consumers may have difficulty identifying which sites sell legitimate products. As FDA considers the issues related to online drug sales, we recognize that there are various types of websites used for drug sales. Many sites focus on selling prescription drugs and are referred to by some as "Internet pharmacies." These sites offer for sale either FDA-approved prescription drug products, or in some cases, unapproved, illegal versions of prescription drugs. In many cases, FDA cannot provide consumers with any assurance that the

drugs purchased over the Internet were manufactured under current good manufacturing practices (cGMP) requirements even if the website appears to be based in the U.S. The Internet sites of legitimate, properly licensed pharmacies provide genuine benefits to consumers. However, sites that are unlicensed or otherwise engaged in the illegal dispensing of prescription drugs pose a serious potential threat to the health and safety of American citizens. While the increase in "Internet pharmacy" sites engaged in illegal sales is seen by some as a particularly potent threat, FDA believes that some of the non-pharmacy sites are also harmful. We have moved aggressively against those other drug sites unlawfully offering unapproved drug products, products making fraudulent health claims, or drugs for recreational use.

Consumers can, and should, be cautious when purchasing drugs online. There is no foolproof way of checking a site's reliability. Although there are legitimate sites that sell drugs, some sites do not employ licensed professionals and may not sell you the real drug. Consumers should check with their State Board of Pharmacy or the National Association of Boards of Pharmacy to see if the online pharmacy possesses a valid pharmacy license and has met state quality standards. In addition, consumers should use the same common sense they would apply to anyone they have never purchased a product from before: Does the site have a good reputation for the service it provides? Have people you trust used them and were they satisfied? If it is a site that cannot be verified – such as an overseas site – it may be best to avoid it. There is usually a local pharmacy that will have what the consumer needs.

FDA AUTHORITY

The unique qualities of the Internet, including its broad reach, relative anonymity, and ease of creating new or removing old websites, pose new challenges for the enforcement of the Food, Drug, and Cosmetic (FD&C) Act. FDA has found that many Internet sites are actually comprised of multiple related sites and links, thereby making investigations much more complex and resource intensive. The global nature of the Internet creates special problems for effective law enforcement. Different approaches to drug approval and marketing in foreign countries further complicate law enforcement issues for U.S. officials. FDA and other U.S. government agencies need to work closely with foreign governments to share information and to develop mechanisms for cooperative law enforcement.

The types of unlawful conduct that can occur when drugs are sold over the Internet are similar to unlawful activities that occur in other contexts. Under the FD&C Act, FDA has the legal authority to take action against:

- The importation, sale, or distribution of an adulterated or misbranded drug;
- The importation, sale, or distribution of an unapproved new drug;
- Illegal promotion of a drug;
- The sale or dispensing of a prescription drug without a valid prescription; and
- Counterfeit drugs.

When the Internet is used for an illegal sale, FDA, working with the Department of Justice (DOJ), must establish the grounds for a case, develop the same charges, and take the same actions as it would if another medium, such as a storefront or a magazine, had been used. FDA has investigated and referred cases for criminal prosecution and initiated civil enforcement actions

against online sellers of drugs and other FDA-regulated products, particularly sellers of drugs not approved by the Agency.

STATE REGULATION OF THE PRACTICE OF MEDICINE, PHARMACY AND DISPENSING OF DRUGS

The states have enacted laws regulating the practice of pharmacy and the practice of medicine to protect patients from harm resulting from the use of unsafe drugs, and the improper practice of medicine and pharmacy. Under many of these laws, to receive a prescription drug, a licensed health care practitioner who determines the appropriate treatment and issues a prescription for an FDA-approved drug generally must examine a patient. The prescription may also authorize refills. The patient then has the prescription filled by a registered pharmacist working in a licensed pharmacy that meets state standards.

These safeguards are not always in place when drugs are purchased over the Internet. A consumer may not be examined by a health care practitioner prior to purchasing drugs online. A patient-doctor relationship, in many cases, is not established. However, attempts to stop some U.S. doctors and online pharmacies from issuing online prescriptions without a physical examination have not always been successful. States face many obstacles when it comes to online pharmacies. State and state medical boards may have limited resources for enforcement and state regulations may currently address the Internet context. There is also the difficulty of prosecuting or taking legal action across state lines. Doctors may or may not be in the same state where the patient lives, so states may have difficulty prosecuting under their existing criminal or consumer protection laws. Only a handful of state legislatures have passed legislation to address issues that arise from online prescribing.

USE OF INTERNET TO BYPASS REGULATORY SYSTEMS

Even with these Federal and state systems in place, the Internet provides ample opportunities for circumventing established safeguards. The speed, ease, and anonymity of ordering products on the Internet can attract unscrupulous sellers. Individuals not licensed to sell prescription drugs can easily create websites that appear to represent legitimate pharmacies. The fact that operators can quickly change the location and appearance of their Internet site makes enforcement all the more difficult. More than many other types of electronic commerce, the unauthorized sale of prescription and unapproved drugs poses a potential threat to the health and safety of consumers.

Patients who buy prescription drugs from an illegitimate site are at risk of suffering adverse events, some of which can be life threatening. These risks include potential side effects from inappropriately prescribed medications, dangerous drug interactions or drug contamination. Patients are also at risk because they often don't know what they are getting when they purchase some of these drugs. Although some patients may purchase genuine product, others may unknowingly buy counterfeit copies that contain inert ingredients, legitimate drugs that are outdated and have been diverted to illegitimate resellers, or dangerous sub-potent or super-potent products that were improperly manufactured. Moreover, consumers who are desperate for a cure to a serious medical problem may be more than willing to accept a product of unknown origin.

FDA is concerned about the proliferation of sites that substitute a simple online questionnaire for a face-to-face examination and patient supervision by a health care practitioner. According to the American Medical Association, a health care practitioner who offers a prescription for a patient he

or she has never seen before, based solely on an online questionnaire, generally does not meet the appropriate medical standard of care. The Federation of State Medical Boards, Special Committee on Professional Conduct and Ethics, has found that "Prescribing of medications by physicians based solely on an electronic medical questionnaire clearly fails to meet an acceptable standard of care and is outside the bounds of professional conduct." This finding is especially important in light of the primary responsibility of states in regulating the practice of medicine. FDA is also concerned that the use of such questionnaires may jeopardize the privacy of a patient's medical records. We will continue to play a role in the Administration's efforts with the private sector to implement appropriate protections for patient's medical information. We also will continue to distinguish legitimate online communications from unlawful conduct that poses risks to patients.

The Agency is equally concerned that in some Internet transactions there is an apparent absence of any health professional/patient relationship. This is a particular concern where a patient may be using a prescription drug for the first time or where the patient may be taking other medications. FDA is concerned that the selection of prescription drug products or treatment regimens for a particular patient should be made with the advice of a licensed health care practitioner who is familiar with the patient's current health status and past medical history. In situations where a customary physician-patient relationship does not exist, the patient may be practicing what amounts to self-diagnosis. Consequently, the risk of negative outcomes such as harmful drug interactions, contraindications, allergic reactions or improper dosing is potentially magnified.

FEDERAL, STATE AND INTERNATIONAL JURISDICTION CHALLENGES

Online drug sales pose unique challenges for regulatory and law enforcement agencies at the state, Federal and international level. Internet technology can obscure the source of the product as well as provide a degree of anonymity to those responsible for selling and shipping the product. The parties to a transaction can be dispersed geographically and usually never meet. Thus, the regulatory and enforcement issues cross state, Federal, and international jurisdictional lines.

The sale of drugs to U.S. residents via foreign websites is an extremely challenging area. Some medications sold on the Internet may be legal in foreign countries but not approved for use in the U.S. Products not approved for sale in the U.S. often do not conform to the GMP and quality assurance requirements in U.S. laws and regulations, and it is illegal for a foreign pharmacy to ship such drugs into the U.S. Foreign sales pose the most difficult challenge for U.S. law enforcement because the seller is not within U.S. boundaries. Although FDA has jurisdiction over a resident in a foreign country who sells in violation of the FD&C Act to a U.S. resident, from a practical standpoint, the Agency has a difficult time enforcing the law against foreign sellers. FDA confronts the same obstacles facing other U.S. regulatory and law enforcement agencies seeking to hold foreign actors accountable for violations of U.S. law. FDA efforts are mostly limited to requesting the foreign government to take action against the seller of the product, or asking the Bureau of Customs and Border Protection (Customs) to stop the imported drug at a U.S. port-of-entry.

Canadian cooperation

On February 21, 2003, FDA representatives participated in a Forum on International Sale of Prescription Drugs from Canada in Ottawa, Canada. The forum was sponsored by the National Association of Pharmacy Regulatory Authorities (NAPRA), the voluntary umbrella association of Canada's provincial and territorial pharmacy licensing bodies. Some of the topics that related to FDA enforcement included: the need for clarification of legal status of international practice in the U.S., the legality of the sale of Canadian drugs to U.S. citizens, risks of the activity for U.S. and Canadian citizens, the legal recourse for any harm caused, the legal issues within the U.S. (at the Federal and state level) and the need to investigate and shut down non-pharmacy operations selling prescription drugs.

In February 2003, FDA participated in a call with officials from Health Canada to discuss his concerns regarding the increasing number of U.S. pharmacies that are advertising and promoting prescription drugs from Canada. FDA shared a list of 45 active websites based in Canada that are selling drugs to U.S. citizens for additional investigation.

Just last week, based on an FDA warning letter to the storefront operation, Rx Depot, the Manitoba Pharmaceutical Association (the pharmacy regulatory authority in the province of Manitoba) told a Manitoba pharmacy filling prescriptions for Rx Depot that the pharmacy that such conduct violates the Standards of Practice and the Code of Ethics in Manitoba. The pharmacy has been given 14 days to provide a satisfactory written response to the Manitoba Pharmaceutical Association or further action may be taken.

ADDITIONAL FDA ACTIVITIES TO PROTECT PUBLIC HEALTH

FDA cannot assure U.S. citizens that the prescription medications they are buying over the Internet from foreign countries such as Canada are safe. Many drugs obtained from foreign sources that either purport to be or appear to be the same as U.S. approved prescription drugs are, in fact, of unknown quality. The rise of Internet drugs sales presents substantial safety questions about these products.

FDA is taking a number of steps to protect the public health of U.S. citizens including: (1) educating the public to the possible safety issues of drugs purchased from foreign countries, (2) working with professional groups to disseminate FDA's message on Internet drug sales, (3) partnering with the individual U.S. states and other Federal agencies to develop enforcement strategies, share cases and discuss important policy issues, and (4) increasing enforcement and policing of rogue Internet sites.

Public Outreach

Public outreach is an important tool that the Agency uses to inform consumers about dangerous or inappropriate drugs. FDA is expanding its public outreach about dangerous practices associated with Internet purchases. We are also conducting outreach to explain what compliance and enforcement actions we already have taken. This effort includes FDA *Talk Papers*, articles in *FDA Consumer* magazine, and information on FDA's website to help educate consumers about

safely purchasing drugs online. FDA's website also provides consumers with an opportunity to submit information to the Agency about sites that may violate the FD&C Act.

FDA remains committed to developing more effective education and enforcement strategies. With this goal in mind, FDA has created public education brochures and posters entitled, "*Things you should know about purchasing medications outside the United States*" to alert consumers to the health risks of buying medications outside the U.S. Outreach to consumers and the media continues, and new public material will be added to FDA's website.

In October 2000, the Division of Public Affairs in FDA's Center for Drug Evaluation and Research (CDER) launched an education campaign on the subject of buying prescription medicines online, entitled, "Shop Smart." This effort is part of FDA's "Buying Rx Drugs Online" education program. The centerpiece of this multi-media campaign is FDA's website: *http://www.fda.gov/oc/buyonline/default.htm* (launched December 1999) that can be accessed from FDA's home page. The website includes information for consumers, including tips and warnings, how to spot health fraud, frequently asked questions (FAQ's) and where to report suspected "rogue" sites. The website is one of the most frequently visited web pages on the FDA website.

Another central piece of our campaign is a brochure entitled, "Buying Prescription Medicines Online: *A Consumer Safety Guide*." The brochure was produced by the CybeRx-Smart Safety Coalition, a partnership of Internet companies, trade associations, health and consumer organizations and other government agencies. The brochure is available in hard copy from FDA, the Federal Consumer Information Center and the National Council for Patient Information and

Education (member of CybeRx-Smart). It is also posted on the FDA web site. The number of consumer complaints received by FDA has grown steadily with the circulation of the brochure.

In addition, the January/February 2001 issue of the *FDA Consumer* magazine included an article entitled, "Buying Drugs Online: It's Convenient and Private, but beware of 'Rogue Sites.'" The article is available online and thousands of reprints have been distributed at conferences and exhibits around the country. To date, the release has generated 644 newspaper articles in 35 different states. In addition, a 30-second radio public service announcement was produced and distributed to stations throughout the U.S. The release has been broadcast on 233 radio stations in 46 different states with an audience of almost 6 million. Two print public service announcements (one for medical devices and one for prescription medicines) were produced and sent to over 100 national magazines. Many Internet drug sites are unknowingly in violation of FDA's regulations, and the "about me" section of the release provides guidance on how to meet FDA requirements.

In November 2001, FDA worked with the Federal Trade Commission (FTC) and the Centers for Disease Control and Prevention to produce a National Association of Boards of Pharmacy (NABP) newsletter article on Cipro and the dangers of buying antibiotics to treat biological threats over the Internet. The article is an abbreviated version of the FTC alert, which was posted on its website in October 2001. FDA's website continues to update and post frequently asked questions (FAQ's), warning letters, talk papers, etc. on the subject of Cipro and other antibiotics.

The Agency will continue working with consumer groups, health care practitioner organizations, and industry to encourage all parties to keep their constituents and the public informed about safe practices for purchasing drugs online.

Professional Outreach and Partnering

At the February 1999 meeting of health professional organizations, FDA, the Federation of State Medical Boards of the United States, the NABP, the American Medical Association and the Association of Food and Drug Officials discussed the roles of each organization in regulating prescribing and dispensing medication via the Internet and how the various roles could better complement each other. At that meeting, the NABP announced its program to verify the legitimacy of Internet sites dispensing prescription drugs. The program, known as the Verified Internet Pharmacy Practice Sites, or VIPPS, provides a NABP "seal of approval" to sites that apply and meet state licensure requirements and NABP's standards. Over time, this seal of approval may help to assure consumers that the designated sites are offering FDA approved pharmaceuticals. The VIPPS program is voluntary and requires the applicant to pay a fee.

FDA continues to meet with organizations representing state regulatory and law enforcement bodies, consumers, health care practitioners and industry. The purpose of these meetings is to gather information on: 1) how issues relating to online drug sales should be addressed, 2) who should regulate and how they should regulate, 3) whether and what changes to the current law should be enacted, and 4) when to develop partnering arrangements. The organizations we are meeting with include:

- The National Association of Boards of Pharmacy
- The Federation of State Medical Boards
- The National Association of Attorneys General
- The American Medical Association
- The American Pharmaceutical Association

- AARP
- The National Consumers League
- The American Society of Health-Systems Pharmacists
- The National Association of Chain Drug Stores
- The National Community Pharmacists Association
- The Pharmaceutical Research and Manufacturers Association
- Pharmaceutical Security Institute

Coordination with State and Federal Agencies

Several Federal agencies, as well as the states, have the authority to regulate and/or enforce U.S. laws related to the sale of drug products online. Due to the growth of potential cases involving the Internet, there are instances when working with another agency or state yields a more effective enforcement result. Working closely with the states is essential to effectively regulate the sale of drugs, as well as the sale of prescription drugs without a valid prescription over the Internet. FDA has established partnership agreements with several state bodies, including the National Association of Boards of Pharmacies and the Federation of State Medical Boards, to coordinate Federal and state activities aimed at questionable practices associated with the selling and prescribing of prescription drugs over the Internet.

Two weeks ago, acting in conjunction with action by the Arkansas State Board of Pharmacy, FDA issued a warning letter to Rx Depot, a storefront operation. The letter put the firm on notice that FDA considers their operation to be a risk to public health. The Arkansas State Board of Pharmacy issued their own letter to the firm instructing them to cease violating state law immediately. Rx Depot and similar companies often state incorrectly to consumers that FDA

condones their activities and even that their prescription medications are "FDA approved," which could lead consumers to conclude mistakenly that the prescription drugs sold by the companies have the same assurance of safety as drugs actually regulated by FDA. FDA believes that operations such as this one expose the public to significant potential risks associated with unregulated imported prescription medicines.

In addition, FDA stated on March 27, 2003, that the Agency supports the joint actions of the state of Oklahoma State Board of Pharmacy and the Oklahoma Attorney General's Office petition for injunction seeking to stop the Rx Deport storefront operation from violating state laws. The state authorities filed a petition in Oklahoma state court, alleging that Rx Depot is illegally operating an unlicensed pharmacy.

As these actions indicate, FDA intends to work closely with its partners in the individual states in support of their efforts to curtain illegal and potentially dangerous operations, especially when they involve misleading claims about drug safety. FDA has been working closely with states on illegal Internet pharmacy issues over the past four year to protect the public health.

FDA has increased coordination with other governmental bodies and has met several times over the past year with other Federal agencies and state officials to share information, discuss the roles and responsibilities of the parties regarding online drug sales and identify opportunities for partnering in enforcement actions. FDA maintains strong working relationships with the DOJ, including the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI), the U.S. Postal Inspection Service, Customs and other appropriate Federal and state

agencies. FDA believes that cooperation among Federal agencies is particularly critical to address the sale of drugs to U.S. residents by foreign sellers. Customs, the U.S. Postal Service, FDA, and the DEA all have important responsibilities in countering the illegal importation of drugs.

FDA determines when and with whom to engage in joint enforcement activities based on the type and severity of conduct identified through various means, including Internet monitoring. Although FDA is expanding its own Internet monitoring capabilities, the Agency also is developing partnerships in this area with other agencies.

Enhanced Enforcement Activities

FDA has conducted investigation and enforcement activities relating to Internet drug sales by re-deploying FDA personnel, which necessarily results in a reduction of investigation and enforcement activity in other areas. The Agency has taken action because we believe that illegal online drug sales pose a significant public health risk. FDA has initially focused its online drug sales-related enforcement activities in the following areas, particularly where there is a significant public health risk:

- Unapproved new drugs;
- Health fraud; and
- Prescription drugs sold without a valid prescription.

FDA has increased its capability to monitor the Internet and identify sites that potentially violate the FD&C Act through the use of various search tools and by upgrading its data handling

capabilities. These actions help the Agency to better understand the type and extent of unlawful conduct on the Internet and to more accurately assess whether its enforcement efforts have had an impact on illegal behavior.

Over the last three years, in an attempt to better comprehend the universe of websites selling drugs, the Office of Criminal Investigation (OCI) has reviewed thousands of websites and identified hundreds involved in the sale of drug products. This review was based on an electronic search of websites, followed by a manual review of sites that appeared to involve the sale of drug products. Because new websites are launched everyday and old websites are taken down, the total number of these sites changes over time.

In June 1999, FDA established a case assessment or "triage" team with representatives from the Office of Enforcement and OCI within the Office of Regulatory Affairs (ORA), the Center for Drug Evaluation and Research (CDER), the Office of Chief Counsel (OCC) and the Office of Policy. Under the triage process, FDA obtains leads on sites that potentially violate the FD&C Act from internal Internet monitoring activity, state, other Federal or foreign law enforcement agencies, consumers, Congress, and the press. The triage team evaluates leads and decides whether they should be pursued through a civil or criminal investigation. Priority is given to cases involving unapproved new drugs, health fraud, and prescription drugs sold without a valid prescription and products with the potential for causing serious or life-threatening reactions. The triage team makes referrals, when appropriate, for FDA follow-up.

The triage process results in a better coordination of criminal and civil enforcement actions at the appropriate Agency components and reduces overlapping effort. This process helps to ensure that decisions are made in a timely way. The Agency seeks an appropriate balance in terms of achieving a maximum deterrent effect while taking action, if needed, to remove harmful products from the market. The team will continue to oversee Internet-related enforcement activities while they are being investigated, and will ensure that they are brought to appropriate conclusion. In addition, the scope of this group is being expanded to cover all FDA-regulated products.

OCI, working with OCC, is responsible for investigations of pharmacy sites and other Internet drug sites whose operations involve potential criminal activity. The Investigative Analysis Branch analyzes the information collected by OCI. After the suspect sites are researched, and possible violations are identified, the OCI field offices receive assignment for investigative work, which often includes undercover buys. Further investigation determines the bona fides of the pharmacy and doctor(s), and examines the relationship between the patient and doctor and the doctor and pharmacy. OCI has ongoing cooperative relationships with Customs, DEA, FBI, the Postal Inspection Service and appropriate state law enforcement and regulatory agencies, and this has enhanced their investigative capabilities with regard to Internet drug sales.

To date, OCI has initiated 372 Internet drug investigations, 90 of which involve domestic Internet pharmacies, with each case involving a variable number of websites from 1 to 25 or more. These cases originated from multiple sources including interception at mail facilities, web-based research, consumer complaints, and a variety of other sources. OCI has effected 150 Internet-related drug arrests, 60 of which involve Internet pharmacy cases, and obtained 92 convictions, 26

of which involve domestic Internet pharmacy cases. OCI currently has approximately 100 open Internet investigations.

Currently, FDA has 90 sites under active review for possible regulatory or civil action. Warning letters have been sent to 55 domestic online sellers. In addition, FDA has sent 137 cyber letters to operators of Internet sites in many countries, including Canada, that offer to sell on-line prescription drugs or unapproved drugs. These sites may be engaged in illegal activity such as offering to sell prescription drugs to U.S. citizens without valid (or in some cases without any) prescriptions. Cyber letters are sent over the Internet to the suspect websites to warn the operators that they may be engaged in illegal activities, and inform them of the laws that govern prescription drug sales in the U.S. FDA also sends copies of its cyber letters to the home governments of targeted websites when the locations can be identified. However, follow-up depends on the ability and willingness of the foreign regulatory bodies to investigate and take actions against website operators who are illegally shipping drugs to other countries.

In cooperation with DOJ, FDA has obtained five preliminary injunctions against the sale of illegal products, including one product marketed as a weight-loss aid containing a potent thyroid hormone that could cause heart attacks or strokes, and an unapproved cancer therapy. The Agency has also conducted 15 product seizures, 11 product recalls, and the voluntary destruction of 18 illegal products (generally pertaining to unapproved new drug products). Finally, FDA has been involved in numerous cases that involve rogue websites. A synopsis of many of these cases is attached to this testimony. (See Attachment) This attachment also lists a number of studies and surveys conducted by FDA to gather data on unapproved drugs coming into the U.S.

Newly revised import alert

On December 9, 2002, FDA reissued import alert 66-41 to include certain drugs approved for restricted use (due to safety concerns) in the U.S. This import alert allows FDA district field investigators to automatically detain without examination the listing of drugs. The Agency has posted this special alert on its home page warning consumers that certain restricted distribution drugs should not be purchased over the Internet. FDA has also put these restricted distribution drugs on Import Alert, informing the Agency's import inspectors that shipments of these drug are not appropriate for admission into this country under FDA's personal importation policy. FDA has also specifically informed Customs about the fact that these dangerous drugs should not be admitted. Imported drugs subject to this import alert are not admissible under FDA's personal importation policy.

The FDA field guidance for this Import Alert provides that release of an unapproved drug for personal use may be appropriate if, among other considerations, the drug is intended for a serious condition for which effective treatment may not be available domestically either through commercial or clinical means, and it is not considered to represent an unreasonable risk. The guidance is intended to apply only to: (1) persons who have received treatment in a foreign country with an unapproved drug that is not available in the U.S., and who, upon returning to the U.S., have imported the drug for their personal use in an effort to continue the treatment started abroad; and (2) persons who have made their own arrangements for obtaining an unapproved drug from foreign sources, when the drug has not been promoted in the U.S.

OTHER FDA ACTIONS THAT MAY RESULT IN REDUCTIONS IN THE COST OF DRUGS

FDA recognizes that part of the concern affecting consumer behavior is the availability of lower costs medications through Internet websites selling foreign products. The Agency is taking various steps that we believe will have a beneficial impact on the cost availability of medications.

Increased resources to speed generic drug review

In Fiscal Year 2003, FDA received a $5.3 million increase to improve review times for generic drug applications. The Agency will use these resources to:

- Hire additional reviewers and inspectors to support generic drug review.
- Make technology upgrades to meet the expected increase in generic drug applications.

This will allow the Agency to set a goal of reviewing 75 percent of generic drug applications within 6 months after submission and better monitor the quality of finished drug products and bulk drug substances entering the U.S. from overseas.

In Fiscal Year 2004, the Administration proposes a $13 million increase for the Generic Drug Program to expand the development of generic alternatives and further improve review times for generic drug applications. FDA will use this proposed increase to:

- Establish manufacturing monographs and standards for bioequivalence, so that generic drug products can be developed in additional product areas.

- Hire more review staff to complete review and action on 90 percent or more of original applications within 180 days and decrease median approval time.

- Hire more field investigators for inspections of generic manufacturing firms to allow faster action on generic drug applications.

- Enhance Internet technology capabilities to support electronic submissions for generic drug applications.
- Increase Agency external collaborations to improve information for prescribers and consumers to ensure safe and effective use of generic drugs.

FDA also has proposed regulatory changes designed to limit delays in generic drug availability due to patent extensions. FDA's proposal would speed generic drugs to market, achieving an estimated $35 billion in savings for American consumers over 10 years. Specifically, the proposed rule would allow only one thirty-month stay per generic drug application, clarify that certain patents cannot be listed, and beef up the declaration that innovators must make about the patents they submit to FDA for listing in the Orange Book.

The proposed rule was published on October 24, 2002, and the comment period ended on December 23, 2003. FDA is currently finalizing the review of the comments and plans to issue a final rule in the coming months.

New Drug Development

FDA is taking steps to support market competition as a means of addressing the cost of developing and manufacturing drugs, and the availability of generic drug alternatives. Two new FDA initiatives in the Agency's Strategic Action plan address important factors affecting the cost of new drug development and the cost of drug manufacturing.

New drug development presents uncertainties that increase the business risk and costs to the innovator. Higher costs can create barriers to competition for new drugs and new innovators**,** companies that don't have access to the capital available to more established drug companies.

Although some scientific and technical uncertainties are inherent and unavoidable in drug innovation, others can be reduced or eliminated. This will help speed patient access to new drugs and reduce the cost of drug development. FDA has begun major initiatives to reduce those sources of uncertainty.

Sponsors may be uncertain about what specific evidence is required to demonstrate safety and effectiveness for a given disease. As a result, they may continue research with a drug that will not lead to the required evidence.

FDA has identified several priority disease areas and new technologies that the Agency believes are good candidates for new work to clarify regulatory pathways and clinical endpoints. The targeted disease areas include cancer, diabetes and obesity. The targeted technologies include cell and gene therapy, pharmacogenomics and novel drug delivery systems.

A planned formal guidance for industry will help to minimize guesswork and improve the design of clinical trials. This will benefit participating patients and allow more cost effective use of Research and Development funds. FDA is also taking steps to identify and address the root causes of avoidable delays in new drug review through retrospective analysis, better review

management and prospective evaluation of our review process from the perspective of both FDA and drug innovators.

CONCLUSION

Mr. Chairman, online shopping for pharmaceutical products clearly provides many benefits for consumers. However, it also poses a number of significant risks. In addition, the nature of Internet technology presents law enforcement and policy makers with unique challenges. FDA is grappling with these challenges including our need to carefully balance consumer access to information and products with protecting the public health. We are using our existing compliance and enforcement tools to prevent consumers from obtaining adulterated and/or misbranded FDA regulated goods via the Internet and will continue to evaluate what changes in our procedures, regulations, or the law might be appropriate to enhance our efforts. Our goal is to ensure that the protections afforded to consumers who purchase drugs from their corner drugstore also extend to consumers in the electronic marketplace.

We look forward to working further with Congress on this important issue, and I would be happy to answer any questions you may have.

ATTACHMENT

FDA CASES AND STUDIES

CASES

Norfolk Men's Clinic

On February 16, 2002, a Federal jury in Alabama convicted Anton Pusztai and Anita Yates of charges arising out of the operation of the online pharmacy that illegally sold prescription drugs over the Internet to consumers. On June 18, Pusztai and Yates were sentenced respectively to more than 15 and 6.5 years. Pusztai, an Australian citizen, and Yates, a resident of Clanton, Alabama, were convicted of conspiracy to commit violations of the FD&C Act, conspiracy to commit money laundering, mail fraud, dispensing misbranded drugs, and operating a drug repackaging facility not registered with FDA. From fall 1998 to the summer of 2000, the defendants operated a website called *Viagra.au.com*, also known as Norfolk Men's Clinic, and related sites, that sold a variety of prescription medications.

In September 1999, OCI received information regarding the Norfolk Men's Clinic and the website. Based on this information, several covert purchases were made via the Internet. Search warrants were executed in October 1999 that resulted in the seizure of prescription drugs and business records. Based on these purchases and information gathered through numerous interviews, several individuals were indicted. In addition to defendants Pusztai and Yates, the president of a prescription drug wholesaler located in Miami, Florida, and the company itself, pled guilty to distributing misbranded drugs.

The company also plead guilty to obstruction of justice. In conjunction with the indictment, a second search warrant was executed in Clanton, Alabama, along with two search warrants in West Virginia. While most of the drugs sold in this operation were domestic product, some appeared to have originated in New Zealand.

Dr. Mario Alvarez-Valentin

On January 11, 2002, Dr. Mario Alvarez-Valentin was sentenced to 26 months imprisonment after pleading guilty to wire fraud in connection with the unlawful sale of Viagra over the Internet. Alvarez was a physician contracted with Internet websites for the purpose of authorizing prescriptions for Viagra to persons throughout the U.S. From April 2000 to January 2001, Alvarez, who was only licensed to practice in Puerto Rico, prescribed and caused to be prescribed more than 4,000 prescriptions for Viagra. In doing so, he violated the licensing laws of at least 20 states. United States v. Alvarez-Valentin, D.P.R.

Kwikmed

On October 1, 2002, a Federal Grand Jury in Arizona returned a 198 count indictment against Kwikmed, Inc., Cymedic Health Group, Inc., four owners of these corporations, and two physicians associated with the corporations. The indictment alleges that defendants operated Internet websites, two of which include *kwikmed.com and cymedic.com*, through which they sold prescription drugs, including Viagra, Celebrex, Xenial, and Propecia. The websites did not require a consumer to have a prescription

before receiving the drugs. Instead the customers were required to complete a questionnaire, which the website told customers would be reviewed by a physician.

Customers were charged a fee for this purported medical consultation. The indictment alleges, however, that for the overwhelming majority of applications, no medical reviews, consultations, or physical examinations by a physician took place before drugs were shipped to customers. The indictment also alleges that defendants repackaged drugs obtained from a drug wholesaler, even though defendants were not a registered manufacturer or a licensed pharmacy, and that there was never a licensed pharmacist in any way involved. The indictment also alleges that the drugs dispensed were adulterated because of the defendants' failure to follow cGMP in packaging, holding, and labeling of the drugs. The indictment alleges that during the course of the conspiracy the defendants and others generated sales in excess of $28 million, which was billed to consumers as charges for prescription drugs, doctor consultations, and shipping. These sales resulted from the defendants' distribution of at least 48,816 new orders for prescription drugs and 41,817 refills of those orders. The indictment charges defendants with several violations of the FD&C Act, as well as conspiracy, mail fraud, and money laundering. The charges were the result of an investigation by FDA and the U.S. Postal Inspection Service.

United States v. Carl David Roberts, (E.D. Tenn.).

On January 15, 2003, Roberts was sentenced to a prison term of 57 months. Roberts was chief administrator of an Internet business that used sophisticated technology to sell prescription drugs, including Schedule II narcotics, without any medical supervision.

He had directed an organization that sold drugs from within the U.S., and from abroad. His organization included drug suppliers from Mexico, the Netherlands, and Ecuador. In September 2002, he pled guilty to distribution of controlled substances and conspiracy to violate the FD&C Act.

United States v. Kimball, (11th Circuit).

On May 14, 2002, the Eleventh Circuit affirmed the district court's sentence. Kimball received a 13-year sentence for violating the FD&C Act. Kimball was found guilty after trial of putting prescription drugs into commerce without a prescription. His marketing efforts included use of the Internet.

Medications Express

On June 7, 2001, Gerald Bevins was convicted in U.S. District Court for the Southern District of California of conspiracy to defraud the U.S. and commit offenses against the U.S. by introducing misbranded drugs into interstate commerce and smuggling. On September 4, 2001, Bevins was sentenced to serve twenty-four months in prison. The case was initiated on information received from Customs concerning an Internet website called Medications Express. Bevins sold Mexican prescription pharmaceuticals from this website and claimed that no doctor's prescription was necessary. He continued to sell Mexican prescription pharmaceuticals through the mail from Sun City, California, even after discontinuing the Medications Express website. Bevins, his wife and daughter would receive orders via mail, travel to Tijuana, Mexico, to purchase the pharmaceuticals, and smuggle them back into the U.S. The three packaged the

pharmaceuticals into commercial courier boxes and shipped them to customers around the U.S. The drugs supplied by Bevins were labeled in Spanish.

Canadian Drug Store, Inc.

On May 14, 2002, the Ontario College of Pharmacists, a Canadian government agency, filed charges under Ontario law against The Canadian Drug Store, Inc., for unlawfully operating an unlicensed pharmacy and using an un-registered pharmacist in filling prescriptions for U.S. residents. The College also filed charges against a licensed pharmacist, pharmacy, and physician in Ontario for helping to facilitate the delivery of prescription and non-prescription drugs to U.S. residents. A drug wholesaler was charged with supplying medications to a non-licensed pharmacy.

According to a statement released by the College, there are many websites selling prescription and non-prescription medicines that have not been accredited as legitimate pharmacies by pharmacy regulators in either Canada or the U.S. Some websites presenting themselves as online "pharmacies" or "drugstores" may be operating without a pharmacy license and dispensing prescriptions without the oversight of a licensed pharmacist.

Total Remedy/Prescription Center II

According to news accounts, a Los Angeles pharmacy and two pharmacists were assessed penalties of almost $90 million in a California Board of Pharmacy proceeding in May 2002 for filling more than 3,500 illegal prescriptions over the Internet. The case

was brought under a state law that creates a requirement to fill a prescription pursuant to a good-faith medical examination. The Internet site concentrated on filling prescriptions for lifestyle drugs such as Viagra and Propecia (Associated Press, 5/29/02).

Pillbox Pharmacy

In March, 2002, a Texas pharmacist, three doctors, two corporations and an individual were charged in a Federal indictment alleging that they conspired to illegally dispense drugs in connection with an Internet pharmacy operation. The indictment charged one pharmacist, three physicians and two corporations, the S&H Script Shop and the Pillbox Medical Center, with conspiring to illegally dispense controlled substances and commit money laundering. According to the indictment, between January 1, 2000, and June 12, 2001, the defendants grossed more than $7.7 million from the Internet sales of just two drugs alone. The indictment alleges the doctors would issue prescriptions without establishing a patient history, performing a mental or physical exam, using appropriate diagnostic or laboratory testing, or providing any means to monitor medication response. The charges were the result of an 18-month investigation by FDA, DEA and IRS, working with the U.S. Attorney's office. In April, the pharmacist and two corporations pled guilty to illegally dispensing controlled substances, and agreed to forfeit $1 million.

STUDIES

Carson mail study

In early 2001, FDA and Customs conducted a survey of imported drug products entering the U.S. through the Carson City, California mail facility (the Carson pilot). The

purpose of the Carson pilot was to examine incoming mail shipments of pharmaceutical products over a specified time frame to identify both the volume and the types of drug products entering the U.S. We also wanted to better assess the level of effort and human resources required to handle drug importations at a mail facility, and to better understand the public health implications these importations may have for U.S. consumers.

The Carson pilot ran for a five-week period, with FDA inspectors present for 40 hours per week, a much higher staffing level than is normally possible. Although Customs took a baseline sample which indicated they could have set aside for FDA review an estimated total of 16,500 international packages (650 packages per day), FDA was able to examine only 1,908 packages during the five-week pilot, or an average of 381 packages per week. Unexamined packages were sent on to the addressees. Of the 1,908 packages examined by FDA, 721 parcels (38 percent of the total) originating in 19 countries were detained and the addressees notified that the products appeared to be unapproved for use in the U.S., misbranded and/or a drug requiring a doctor's prescription.

Analysis of the Carson Pilot Drug Parcels

FDA's Center for Drug Evaluation and Research (CDER) reviewed listings of the products detained during the Carson pilot to define better the nature of the risk to public health from the types of products coming into the U.S. through personal importation. CDER's review demonstrates that there are serious public health risks associated with many of the 721 drug shipments (composed of 197 different drugs) detained at Carson. There are primarily two types of risks that consumers of these drugs would face.

The first risk arises when consumers take drugs of unknown origin or quality. Second is the very significant risk associated with taking many of these drugs without first obtaining a physician's prescription and without the continued oversight of the physician.

In general, FDA has no information to establish where these drugs were actually manufactured and whether current GMP requirements were followed. There is also no assurance that the drugs were packaged and stored under appropriate conditions to avoid degradation or contamination. Approximately eight percent of the shipments contained drugs that could not be identified because they contained no labeling; some of these contain only foreign language labeling. Most of these drug shipments were contained in plastic bags; one shipment contained drugs taped between magazine pages.

Several drugs do not appear to correspond with any FDA-approved drugs and therefore the risks associated with the products are difficult to assess. One drug had been reviewed for FDA approval but was rejected because its efficacy could not be demonstrated. Several shipments contained three drugs that were once approved by FDA but have been withdrawn from the market.

The vast majority of the shipments were identified as containing prescription drugs. A number of controlled substances were also identified. Importation of these drugs containing controlled substances violates criminal provisions of the Controlled Substances Import and Export Act, including 21 U.S.C. 960 (unregistered importer/declared importation). These drugs have the potential for abuse, addiction or

risk of life-threatening overdose. A physician's prescription and oversight are essential for managing these risks. Additionally, drugs to treat diseases including diabetes, hypertension and serious infection were included in the Carson shipments, as were many drugs with serious contraindications and/or possible drug or food interactions.

Many of the drugs identified in the Carson pilot are intended to treat conditions that only physicians can properly diagnose. Consumers who bypass physician diagnosis and prescribing may be exposing themselves to risks and toxicities that cannot be justified by offsetting benefits. For example, almost ten percent of the shipments were for antibiotics, despite the fact that consumers are generally not able to diagnose whether their symptoms are caused by bacterial or viral infections.

Three Surveys

Within the last two years, FDA has conducted three surveys at U.S. borders to gather data on drug products carried by individuals entering the U.S. While these border surveys involve land traffic rather than mail importation, the results show some similarities to the findings from the Carson mail pilot, but also some significant differences.

Southwest Border Survey (August 2000)

A survey of prescription drugs being brought by pedestrians into the U.S. at eight ports-of-entry along the 2,000-mile border with Mexico was conducted by FDA's Southwest Import District (SWID) with the assistance of other agencies. The survey looked at activity during four hours on a Saturday (August 12, 2000) at eight border ports in

California, Arizona, and Texas. The purpose of the survey was to determine what specific types of products are being imported, and who is importing these products. The data collected from over 600 interviews indicated that the most common importers were bringing back primarily antibiotics or pain relievers. Prescriptions were held by 63 percent of the persons interviewed (59 percent U.S. prescriptions while 41 percent were Mexican). While many of these products are already available as FDA-approved drugs in the U.S., some are unapproved for sale in this country.

Canadian Border Survey

On January 6, 2001, in cooperation with Customs, FDA conducted a survey to obtain a snapshot of prescription drug products being brought into the U.S. from Canada via passenger vehicles. During the eight-hour survey at three ports-of-entry in New York, Michigan and Washington, a total of 10,374 passenger vehicles and 58 buses crossed into the U.S. Of these, 33 passenger vehicles (35 individuals) were referred by Customs to be interviewed. These individuals brought in a total of 47 containers of drug products from Canada. The largest group of products was pain medicines. The next largest group of products was herbal products, with the reason for importation being that the products were not available in the U.S. Some of these drugs are unapproved foreign versions of FDA-approved drugs, although some approved for sale as prescription drugs in the U.S. are sold as over-the-counter medications in Canada.

Southwest Border Survey (April 2001)

On April 11, 2001, FDA, Customs, and other agencies conducted a survey of prescription drugs being brought into the U.S. at seven ports-of-entry along the U.S./Mexican border. During the four-hour survey, a total of 586 persons imported in a total of 1,120 drugs. Approximately 56 percent had a prescription for the medicines (61 percent were U.S. prescriptions, 39 percent were Mexican). As in the earlier survey, many of these products are already available as FDA-approved drugs in the U.S., while some are unapproved for sale in this country.